## PRELIMINARY WORKING DRAFT - DO NOT COPY OR QUOTE

## 2.0 INTRODUCTION

The purpose of this report is to provide a firm basis for completing a state-of-the-art-protocol to assess potential human-health risks associated with exposure to asbestos. Such a protocol is intended specifically for use in performing risk assessments at Superfund sites, although it may be applicable to a broad range of situations.

The approach currently employed at the U.S. Environmental Protection Agency (U.S. EPA) to evaluate asbestos-related risks (IRIS 1988) is based primarily on a document completed in 1986 (U.S. EPA 1986) and has not been changed substantially in the past 15 years, despite substantial improvements in asbestos measurement techniques and in the understanding of the manner in which asbestos exposure contributes to disease. Therefore, this document provides an overview and evaluation of the more recent studies and presents proposed modifications to the protocol for assessing asbestos-related risks that can be justified based on the more recent work.

In May, 2001, the U.S. EPA along with the California Environmental Protection Agency (Cal EPA), the National Institute for Occupational Safety and Health (NIOSH), the American Toxic Substances Disease Registry (ATSDR), and the Mine Safety and Health Administration (MSHA) hosted an international conference on asbestos in Oakland. The current state of knowledge (including, particularly, the status of knowledge gaps) was reviewed during this conference by many of the leading researchers. Consequently, several issues were raised concerning the state of knowledge of asbestos. To the extent that such issues are relevant to the assessment of asbestos-related risks, they are considered in this document.

Among the asbestos-related issues that have been the focus of recent attention:

- whether the dose-response models currently in use by the EPA for describing the incidence of asbestos-related diseases adequately reflect the time-dependence for the development of these diseases;
- whether the relative in-vivo durability of different asbestos mineral types affect their relative potency;
- whether the set of minerals included in the current definition of asbestos adequately covers the range of minerals that potentially contribute to asbestos-related diseases;

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- whether the analytical techniques and methods currently used for determining asbestos concentrations adequately capture the biologically relevant characteristics of asbestos (particularly with regard to the sizes of the structures included in the various analyses) so that they can be used to support risk assessment; and
- whether reasonable confidence can be placed in the cross-study extrapolation of dose-response relationships that are required to assess asbestos-related risks in new environments of interest.

These and other asbestos-related issues are described in greater detail in Chapter 3 (Overview) and Chapter 4 (Background).

The studies relevant to developing a protocol are reviewed in this document and combined with supporting analysis to resolve issues and identify the best candidate procedures for assessing asbestos-related risks. Although the objective of this evaluation was to identify the single best procedures, when current knowledge is inadequate for distinguishing among alternatives, options are presented along with a discussion of their relative advantages and limitations. In a few cases, limited and focused additional research studies are recommended, which may enhance the current state of knowledge sufficiently to resolve one or more of the important, remaining issues.

This document is an update to a previous review (Berman and Crump 1999) and primarily incorporates information developed subsequent to the earlier review. It is also the last in a series of documents developed as part of a multi-task project to develop a set of mutually consistent methods for determining asbestos concentrations in a manner useful for assessing risk and a companion protocol for conducting such risk assessments. A method for the determination of asbestos in air (Chatfield and Berman 1990) and a companion technical background document (Berman and Chatfield 1990) were published by the U.S. EPA in 1990. The air method has since been superceded (improved) by the ISO Method (ISO 10312). A method for the determination of asbestos in soils and bulk materials (Berman and Kolk 1997) was also published by the U.S. EPA and the draft of an improved version was also recently completed (Berman and Kolk 2000). The recommendations in this document should serve as the basis for development of the companion risk-assessment protocol.

2.2 Revision 1 – 8/27/01